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## ADDITIONAL INSTRUCTIONS FOR APPLICANTS WITH INSULIN-TREATED DIABETES MELLITUS (ITDM) <sup>1</sup>

**Overview.** MoDOT's Director of Motor Carrier Services may grant an exemption from the physical qualification for drivers of commercial motor vehicles (CMVs) required by 49 CFR § 391.41(b)(3), which requires that a driver "has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control". The Director may grant an exemption by issuing a Skill Performance Evaluation (SPE) Certificate for a period up to two years, if MoDOT finds that: "such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption."<sup>2</sup>

**Publication of Notice of Application.** MoDOT Motor Carrier Services Division must publish a notice of each completed application received, in the *Missouri Register*, explaining that the application has been filed, and inviting the public to inspect the safety analysis and any other relevant information known to MoDOT Motor Carrier Services Division, and to comment on the application. Prior to granting an application for an exemption, MoDOT Motor Carrier Services Division must publish a second notice in the *Missouri Register*, identifying the person or class of persons who will receive the exemption, the provisions from which the person will be exempt, the effective period, and all terms and conditions of the exemption. The terms and conditions established by MoDOT Motor Carrier Services Division must ensure that the exemption will likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with the regulation. In addition, MoDOT is required to monitor the implementation of each exemption to ensure compliance with its terms and conditions. If the Director denies an application for an exemption, MoDOT Motor Carrier Services Division must publish a notice in the *Missouri Register* identifying the person whose application is denied, and the reasons for the denial.

**Renewal and Revocation of Exemption.** Generally, the duration of an exemption is limited to not more than two years from the date of approval, but may be renewable upon application to the Director. MoDOT Motor Carrier Services Division is required immediately to revoke an exemption if: (1) The person fails to comply with the terms and conditions of the exemption; (2) The exemption has resulted in a lower level of safety than was maintained before the exemption was granted; or (3) Continuation of the exemption would not be consistent with the goals and objectives of the exemption regulations.

**Obtaining an Application Packet.** Persons who desire to apply for an exemption may mail requests for an application packet to: MoDOT Motor Carrier Services Division, Medical Exemption Program, P.O. Box 893, Jefferson City, MO 65102-0893, or may telephone Kathy Hatfield, Motor Carrier Specialist, at 573-522-9001, or (toll free) 866-831-6277. MoDOT will mail the required forms and instructions.

**Procedures for Applying for an Exemption.** Procedures for the review of exemption applications require MoDOT Motor Carrier Services Division to review a completed application for an exemption, and to prepare, for the Director's signature, a *Missouri Register* notice requesting public comment. After a review of the comments received, MoDOT Motor Carrier Services Division will make a recommendation to the Director. MoDOT will publish a notice of the Director's final decision in the *Missouri Register*. The Director will issue a final decision within 180 days of the date MoDOT Motor Carrier Services Division receives an individual's completed application packet. However, if the applicant should omit important details or other information necessary for MoDOT Motor Carrier Services Division to conduct a comprehensive evaluation, the Director will issue a final decision within 180 days of the date that it receives sufficient information. MoDOT recognizes that this potential six-month waiting period may seem burdensome. However, MoDOT must carefully evaluate each and every application for regulatory

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<sup>1</sup> Adapted from: Authority--Insulin-Treated Diabetes Exemptions Under 49 U.S.C. 31315 and 31336(e), Federal Register, September 3, 2003 (Volume 68, Number 170) (Notice of Final Disposition); see also Section 622.555, Missouri Revised Statutes (RSMo) Supp. 2002; MoDOT Administrative Rule 7 CSR 10-25.010.

<sup>2</sup> 68 Fed. Reg. 52442.

relief from the diabetes standard, to assess the potential safety performance of each applicant. In addition, MoDOT must prepare and publish notice of each application in the *Missouri Register*, and then must evaluate comments received before the Director makes a final decision. MoDOT's overriding concern is to ensure the safety of intrastate CMV operations. MoDOT will notify all applicants in writing once the Director makes a final decision.

**Application Requirements.** Every applicant for an exemption must submit an application using MoDOT's completed **SPEC-3 FORM**, and must include all supporting documentation. In considering exemptions by applicants with ITDM, MoDOT Motor Carrier Services Division must ensure that the issuance of a diabetes exemption will not be contrary to the public interest, and that the exemption achieves an acceptable level of safety. MoDOT Motor Carrier Services Division will only grant exemptions; therefore, to ITDM applicants who meet the following requirements:

- (1) **Valid CDL or Drivers License.** Possesses a valid intrastate CDL or a license (non-CDL) to operate a CMV;
- (2) **Minimum Period of Insulin Use.** Has demonstrated stable control of his/her diabetes through a minimum period of insulin use. The minimum period for Type 1 diabetics is 2 months and for Type 2 diabetics is 1 month; however, a longer period may be required if directed by the treating physician;
- (3) **Safe Driving Record.** Has a driving record for the preceding three-year period that: Contains no suspensions or revocations of the applicant's driver's license for the operation of any motor vehicle (including their personal vehicle), Contains no involvement in an accident for which the applicant received a citation for a moving traffic violation while operating a **CMV**, Contains no involvement in an accident for which the applicant contributed to the cause of the accident, and Contains no convictions for a disqualifying offense or more than one serious traffic violation, as defined in 49 CFR 383.5, while operating a **CMV**;
- (4) **No Other Disqualifying Conditions.** Has no other disqualifying physical conditions, including diabetes-related complications, which would make the applicant unable to safely operate a CMV;
- (5) **No Recurrent Hypoglycemic Loss of Consciousness or Seizures.** Has had no recurrent (two or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia;
- (6) **No Recurrent Hypoglycemic Reactions Requiring Assistance.** Has had no recurrent hypoglycemic reactions requiring the assistance of another person within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia;
- (7) **No Recurrent Hypoglycemic Impairment of Cognitive Function.** Has had no recurrent hypoglycemic reactions resulting in impaired cognitive function that occurred without warning symptoms within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia;
- (8) **Endocrinologist Examination.** Has been examined by a board-certified or board-eligible endocrinologist (who is knowledgeable about diabetes) who has conducted a complete medical examination. The complete medical examination must consist of a comprehensive evaluation of the applicant's medical history and current status with a report including the following information:
  - (A) The date insulin use began,
  - (B) Diabetes diagnosis and disease history,
  - (C) Hospitalization records,
  - (D) Consultation notes for diagnostic examinations,
  - (E) Special studies pertaining to the diabetes,
  - (F) Follow-up reports,
  - (G) Reports of any hypoglycemic insulin reactions within the last five years,
  - (H) A current measure of glycosylated hemoglobin (HgA1C), taken during the 30 days immediately before filing the application,
  - (I) Insulin dosages and types, diet utilized for control and any significant factors such as smoking, alcohol use, and other medications or drugs taken, and
  - (J) Examinations to detect any peripheral neuropathy or circulatory insufficiency of the extremities;
- (9) **Endocrinologist Certification.** Submits a signed statement from an examining endocrinologist (which must be submitted using MoDOT's completed **SPEC-F Form**) indicating the following medical determinations: The endocrinologist is familiar with the applicant's medical history for the past five years, either through actual treatment over that time or through consultation with a physician who has treated the applicant during that time; the applicant has been using insulin to control his/her diabetes before the date of the application for the minimum period of insulin use described above; the applicant has been educated in diabetes and its management, thoroughly informed of and understands the procedures which must be followed to monitor and manage his/her diabetes and what procedures should be followed if complications arise; and the applicant has the ability and has demonstrated willingness to properly monitor and manage his/her diabetes; and
- (10) **Ophthalmologist or Optometrist Examination and Certification.** Submits a separate signed statement from an ophthalmologist or optometrist (which must be submitted using MoDOT's completed **SPEC-D Form**) that the applicant has been examined and that the applicant does not have diabetic retinopathy and meets the vision

standard at 49 CFR 391.41(b)(10), or has been issued a valid medical exemption. If the applicant has any evidence of diabetic retinopathy, he or she must be examined by an ophthalmologist and submit a separate signed statement from the ophthalmologist that he or she does not have unstable proliferative diabetic retinopathy (i.e., unstable advancing disease of blood vessels in the retina).

**Special Driving Conditions Required After Issuance of an Exemption to ITDM Individuals.** There are special conditions attached to the issuance of any exemption for ITDM. The Director will impose the following requirements:

- (1) **Medical Supplies for Glucose Management.** Individuals with ITDM shall maintain appropriate medical supplies for glucose management while preparing for the operation of a CMV and during its operation. The supplies shall include the following:
  - (A) An acceptable glucose monitor with memory,
  - (B) Supplies needed to obtain adequate blood samples and to measure blood glucose,
  - (C) Insulin to be used as necessary, and
  - (D) An amount of rapidly absorbable glucose to be used as necessary;
- (2) **Driver's Daily Record.** Individuals with ITDM shall maintain a daily record of actual driving time which must show the times when the driver performs the daily glucose measurements described in the next paragraph; and
- (3) **Monitoring and Maintaining Blood Glucose Levels.** Individuals with ITDM shall self-monitor their blood glucose levels prior to driving, and every two to four hours while driving, using a portable glucose monitoring device equipped with a computerized memory. Prior to and while driving, individuals shall adhere to the following protocol for monitoring and maintaining appropriate blood glucose levels:
  - (1) Check glucose before starting to drive and take corrective action if necessary. If glucose is less than 100 milligrams per deciliter (mg/dl), take glucose or food and recheck in 30 minutes. Do not drive if glucose is less than 100 mg/dl. Repeat the process until glucose is greater than 100 mg/dl;
  - (2) While driving check glucose every two to four hours and take appropriate action to maintain it in the range of 100 to 400 mg/dl;
  - (3) Carry a source of rapidly absorbable glucose, and have food available, at all times when driving. If glucose is less than 100 mg/dl, stop driving and eat. Recheck in 30 minutes and repeat procedure until glucose is greater than 100 mg/dl; and
  - (4) If glucose is greater than 400 mg/dl, stop driving until glucose returns to the 100 to 400 mg/dl range. If more than two hours after last insulin injection and eating, take additional insulin. Recheck blood glucose in 30 minutes. Do not resume driving until glucose is less than 400 mg/dl.

**Follow-up Documentation to Be Provided to MoDOT.** In addition to the requirements for controlling ITDM, MoDOT Motor Carrier Services Division will monitor exemption recipients during the period that the exemption is valid. MoDOT Motor Carrier Services Division will conduct monitoring by requiring the exemption recipients to submit the following information to the Medical Exemption Program, MoDOT Motor Carrier Services Division, P.O. Box 893, Jefferson City, MO 65102.

- (1) **Quarterly - Written Confirmation from Endocrinologist.** Provide written confirmation from the endocrinologist on a quarterly basis:
  - (A) The make and model of the glucose monitoring device with memory;
  - (B) The individual's blood glucose measurements and glycosylated hemoglobin are generally in an adequate range based on:
    - a. All daily glucose measurements taken with the glucose monitoring device and correlated with the daily records of driving time; and
    - b. A current measurement of glycosylated hemoglobin.
- (2) **Annually - Comprehensive Medical Evaluation by Endocrinologist.** Submit on an annual basis, a comprehensive medical evaluation by an endocrinologist. The evaluation will include a general physical examination and a report of glycosylated hemoglobin concentration. The evaluation will also involve an assessment of the individual's willingness and ability to monitor and manage the diabetic condition;
- (3) **Annually - Confirmation of No Diabetic Retinopathy.** Provide on an annual basis confirmation by an ophthalmologist or optometrist that there is no diabetic retinopathy and the individual meets the current vision standards at 49 CFR 391.41(b)(10). If there is any evidence of diabetic retinopathy, provide annual documentation by an ophthalmologist that the individual does not have unstable proliferative diabetic retinopathy;
- (4) **Annually - Documentation of Ongoing Education.** Submit annual documentation by an endocrinologist of ongoing education in management of diabetes and hypoglycemia awareness;
- (5) **Report All Episodes Relating to Diabetes.** Report all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; and
- (6) **Report Any Accident Involvement.** Report any involvement in an accident or any other adverse event whether or not they are related to an episode of hypoglycemia.

**Medical Examination-Certificate of Physical Examination.** Because diabetes is a chronic disease requiring constant control and monitoring, MoDOT Motor Carrier Services Division will impose conditions on ITDM individuals who have been issued an exemption. The required conditions include the following:

- (1) **Yearly Physical Examination.** Each individual must have a physical examination every year:
  - (a) The physical examination must first be conducted by an endocrinologist indicating the driver is:
    1. Free of insulin reactions. "Free of insulin reactions" in this context means that the individual has had:
      - (A) No recurrent (two or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia,
      - (B) No recurrent hypoglycemic reactions requiring the assistance of another person within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia, and
      - (C) No recurrent hypoglycemic reactions resulting in impaired cognitive function that occurred without warning symptoms within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia,
    2. Able to and has demonstrated willingness to properly monitor and manage his/her diabetes, and
    3. Will not likely suffer any diminution in driving ability due to his/her diabetic condition; and
  - (b) Secondly, the physical examination must be conducted by a medical examiner who attests that the individual is physically qualified under 49 CFR 391.41, or holds a valid exemption or SPE Certificate.
- (2) **Compliance Conditions.** Each individual must agree to and must comply with the following conditions:
  - (a) Submit blood glucose records to both the endocrinologist and medical examiner at the annual examinations or when otherwise directed by an authorized agent of MoDOT Motor Carrier Services Division; and
  - (b) Provide a copy of the endocrinologist's report to the medical examiner at the time of the annual medical examination; and
- (3) **Provide Report Indicating No Diabetic Retinopathy.** Each individual must provide a copy of the optometrist's or ophthalmologist's report indicating that there is no diabetic retinopathy and the individual meets the current vision standards at 49 CFR 391.41(b)(10). If there is any evidence of diabetic retinopathy, the individual must provide to the medical examiner at the time of the annual medical examination a copy of the ophthalmologist's report indicating that the individual does not have unstable proliferative diabetic retinopathy; and
- (4) **Provide Annual Medical Certification To Employer.** Each individual must provide a copy of the annual medical certification to the employer for retention in the driver's **qualification** file, or must keep a copy in his/her driver's **qualification** file if he/she is self-employed. The driver must also have a copy of the certification when driving for presentation to a duly authorized Federal, State, or local enforcement official.